Print Clear

Additional pharmacy staff (pharmacists or pharmacy technicians) may be listed below:

7. _____ RPH # _____ Exp. Date: _____

8. _____ RPH # _____ Exp. Date: _____

9. _____ RPH # _____ Exp. Date: _____

10. _____ RPH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

LEGAL REFERENCES used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&PC], Chapter 9, Division 2) can be found in the *California Pharmacy Law.*

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law*.

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

BOARD PUBLICATIONS
(*Intern/Preceptor Manual* and *Candidate's Review Guide)* may be obtained by contacting:

Department of General Services
Documents & Publications Section
P.O. Box 1015
North Highlands CA 95660
(916) 574-2200

CALIFORNIA PHARMACY LAW may be obtained by contacting:

Law Tech
1060 Calle Cordillera, Suite 105
San Clemente CA 92673
(800) 498-0911 Ext. 74
www.lawtech-pub.com

TRIPLICATE FORMS may be obtained from:

Bureau of Narcotic Enforcement
P.O. Box 161089
Sacramento CA 95816
(916) 227-4050

The DRUG ENFORCEMENT ADMINISTRATION may be contacted at:

DEA
255 East Temple Street, 20th Floor
Los Angeles CA 90012
(213) 894-2216, 2217, 4697, or 6711
(213) 894-4016 (Diversion or Investigation)

DEA
450 Golden Gate Avenue
San Francisco CA 94102
(415) 436-7900
(415) 436-7854 (Theft Reports or Diversion)

DEA
1860 Howe Avenue
Sacramento CA 95825
(916) 566-7160

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento CA 95814
Phone: (916) 445-5014
Fax: (916) 327-6308

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

COMMUNITY PHARMACY AND PRACTICE SELF-ASSESSMENT (INCLUDING HOSPITAL PHARMACY THAT DISPENSES PRESCRIPTIONS)

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO," enter an explanation on "COMMENTS" lines below. If more space is needed, you may add additional sheets.

Yes No N/A

1. Facility

- ☐ ☐ ☐ The pharmacy has an area suitable for confidential patient consultation. (CCR 1714, 1764)
- ☐ ☐ ☐ The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, CCR 1714)
- ☐ ☐ ☐ The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
- ☐ ☐ ☐ The pharmacy premises, fixtures and equipment are maintained in a clean and orderly condition. (CCR 1714)
- ☐ ☐ ☐ The pharmacy is kept well-ventilated to ensure drugs are stored at their requisite temperatures. This includes hours when the pharmacy is closed for business. (CCR 1714)
- ☐ ☐ ☐ The pharmacy sink has hot and cold running water. (CCR 1714)
- ☐ ☐ ☐ The pharmacy has a readily accessible restroom. (CCR 1714)
- ☐ ☐ ☐ The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

COMMENTS: _____

_____

a. Compounding Area for Parenteral Solutions (if applicable)

- ☐ ☐ ☐ The pharmacy has a designated area for the preparation of sterile products that has the following: (If not applicable, check N/A and move to Section 2.)
- ☐ ☐ ☐ • A laminar air flow hood or clean room in accordance with Federal Standard 209(b). (CCR 1751[d])
- ☐ ☐ ☐ • Nonporous and cleanable surfaces including the walls, floors and floor coverings. (CCR 1751[b])
- ☐ ☐ ☐ • Sufficient space, well separated from the laminar flow hood area, for the storage of bulk materials, equipment and waste materials. (CCR 1751[e])
- ☐ ☐ ☐ • Ventilation that does not interfere with laminar air flow. (CCR 1751[c])
- ☐ ☐ ☐ • A sink with hot and cold running water within the parenteral solution compounding area or adjacent to it. (CCR 1751[f])

Yes No N/A

- A vertical laminar air flow hood in which the preparation of parenteral cytotoxic agents is performed and in accordance with section 505.11.1 of Title 24 CCR. (CCR 1751.1)
- Gowns and gloves are worn when preparing cytotoxic agents. (CCR 1751.4)
- Certification of all laminar air flow hoods completed at least annually, and records are maintained on file for at least three years. (CCR 1751[d], 1751.1)
- Current reference materials (relating to the drugs and chemicals used in all parenteral therapy services and all parenteral therapy compounding, dispensing, distribution and counseling services provided) are available to the pharmacy. (CCR 1751.9)

COMMENTS: _____

b. Training of Staff, Patient and Caregiver

Consultation is available to the patient and/or primary caregiver concerning proper use of parenterals and related supplies furnished by the pharmacy. (CCR 1751.5)

The pharmacist-in-charge (PIC) is responsible for ensuring that all pharmacy personnel engaging in the compounding of parenteral solutions have training and demonstrated competence in the safe handling and compounding of parenteral solutions, including cytotoxic agents, and is responsible for ensuring their continued competence. (CCR 1751.5)

Records of training and demonstrated competence are available for each individual and are retained for three years beyond each individual's period of employment. (CCR 1751.5)

COMMENTS: _____

c. Quality Assurance

The pharmacy has a documented, ongoing quality assurance program that monitors personnel performance, cleaning and sanitization of the parenteral medication preparation area, and proper storage of final compounded parenteral products. (CCR 1751.7)

The pharmacy has written policies and procedures for handling and disposal of infectious materials and/or materials containing cytotoxic residues (CCR 1751.6)

Written policies and procedures associated with the pharmacy's preparation and furnishing of parenteral products include, but are not limited to: compounding and labeling of intravenous admixtures, administration of intravenous therapy, quality assurance program, recordkeeping requirements, and training staff, patients and caregivers. (CCR 1751.8)

COMMENTS: _____

2. Drug Stock

The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255)

COMMENTS: _____

Yes No N/A

3. Posting of Notices

The "Notice to Consumers" is posted in public view where it can be read by the purchasing public, or written receipts containing the required information are provided to consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. (B&PC 4122, CCR 1707.2)

If applicable, a notice of shared electronic prescription files is posted in public view where it can be read by the purchasing public. (CCR 1717.2)

COMMENTS: _____

4. PIC

The pharmacy has a PIC who is responsible for the pharmacy's compliance with all state and federal pharmacy laws, and who has knowledge and responsibility of the daily operations of the pharmacy. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

The PIC is PIC at only one pharmacy. No pharmacist shall be PIC of more than one pharmacy. Exception: A pharmacist may serve as PIC for two pharmacies if (1) the PIC is the only pharmacist at each pharmacy, and (2) the pharmacies do not have overlapping hours of business. Additionally, the PIC is not serving concurrently as the sole pharmacist for a wholesaler, a medical device retailer or a veterinary food-animal drug retailer. (CCR 1709.1)

COMMENTS: _____

5. Duties of a Pharmacist

The pharmacist receives a new prescription order from the prescriber, consults with the patient, identifies, evaluates and interprets a prescription, interprets the clinical data in a patient medication record, consults with any prescriber, nurse or health professional or agent thereof, supervises the packaging of drugs and checks the packaging procedure and product upon completion, is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients, performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform, and performs all functions which require professional judgment. (B&PC 4051, CCR 1793.1)

The pharmacist as part of the care provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, is performing the following functions, in accordance with policies, procedures or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering or performing routine drug therapy related patient assessment procedures, ordering drug therapy related laboratory tests, administering drugs or biologicals by injection, adjusting the drug regimen of a patient. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052(b). (B&PC 4027, 4051, 4052)

COMMENTS: _____

Yes No N/A

6. Duties of an Intern Pharmacist

☐ Intern pharmacists are performing all the functions of a pharmacist **only** under the direct supervision of a pharmacist, and the pharmacist is supervising no more than one intern at any one time. (B&PC 4114, CCR 1726, 1727)

COMMENTS:_____

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7. Duties of a Pharmacy Technician

☐ Registered pharmacy technicians are performing only packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4038, 4115, CCR 1793.2)

☐ The ratio for technicians performing the tasks above does not exceed one pharmacist to one technician. (B&PC 4038, 4115, CCR 1793.7[f])

☐ A pharmacy technician wears identification identifying him or herself as a pharmacy technician. (CCR 1793.7[d])

☐ The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[e])

8. Duties of a Non-Licensed Personnel

☐ A non-licensed person (clerk-typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and—at the direction of a pharmacist—may request and receive refill authorization. (CCR 1793.3)

☐ The ratio is no greater than one pharmacist to one clerk-typist. (B&PC 4115[g], CCR 1793.3)

COMMENTS:_____

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PHARMACY PRACTICE

9. Consultation/Patient Profile/Review of Drug Therapy

Pharmacists provide oral consultation:

☐ • whenever the prescription drug has not been previously dispensed to the patient (CCR 1707.2)

☐ • whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions (CCR 1707.2)

☐ • upon request (CCR 1707.2)

☐ • whenever the pharmacist deems it warranted in the exercise of his or her professional judgment. (CCR 1707.2)

☐ Appropriate drug warnings and auxiliary labels are provided. (B&PC 4074, CCR 1744)

☐ If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2)

Yes No N/A

The pharmacy maintains patient profile information including allergies, age and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)

The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)

COMMENTS: _____

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10. Corresponding Responsibility for Filling Controlled Substance Prescriptions

Pharmacists are aware of their corresponding responsibility to determine that prescriptions written for controlled substances are issued for **legitimate medical purposes only**. (H&SC 11153)

Before dispensing a prescription that contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain the information needed to validate the prescription. (Even after conferring with the prescriber, the pharmacist never dispenses a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose.) (CCR 1761)

COMMENTS: _____

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11. Prescription Requirements

Prescriptions are complete with all the required information. (B&PC 4040)

Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direct supervision of a pharmacist. (B&PC 4070, CCR 1717)

If a prescription is orally or electronically transmitted, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (B&PC 4071)

If orally transmitted, the pharmacist who received the prescription is identified by initialling the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717)

The security and confidentiality of electronically transmitted prescriptions are maintained. (CCR 1717.4)

The pharmacist does not dispense controlled substances pursuant to preprinted multiple check-off prescription blanks, nor does the pharmacist dispense more than one dangerous drug from preprinted multiple check-off prescription blanks. (CCR 1717.3)

COMMENTS: _____

_____

12. Prescription Labeling and Dispensing

The prescription label contains all the required information in accordance with B&PC 4076.

Expiration dates of drugs' effectiveness are consistent with those of the manufacturer if the information is required on the original manufacturer's label. (B&PC 4076, CCR 1718.1)

The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

Yes	No	N/A	
☐	☐	☐	Generic substitution is communicated to the patient. (B&PC 4073)
☐	☐	☐	If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product. (B&PC 4115, CCR 1793.7)
☐	☐	☐	The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)
☐	☐	☐	Prescriptions are dispensed in new, senior-adult ease-of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)
☐	☐	☐	Patient package inserts are dispensed with all estrogen and progesterone medications. (21 CFR 310.515, 310.516)

COMMENTS: _____

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13. Refill Authorization

☐	☐	☐	Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063)
☐	☐	☐	Refills are documented. (CCR 1717)
☐	☐	☐	Prescriptions for dangerous drugs or devices are refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. The pharmacist informs the prescriber of such refills within a reasonable period of time. (B&PC 4064)
☐	☐	☐	Refills for Schedule II controlled substances are prohibited. (H&SC 11200)
☐	☐	☐	Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120-day supply. (H&SC 11200)

COMMENTS: _____

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14. Prescription Transfer

☐	☐	☐	Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717[f][1-6])
☐	☐	☐	Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

Schedule III, IV and V Controlled Substance Prescription Transfers

☐	☐	☐	For the **transferring pharmacy**: the prescription hard copy is pulled and "void" is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription, and all other information is recorded as required. The prescriptions are transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescriptions are transferred up to the maximum refills permitted by law and the prescriber's authorization. (21 CFR 1306.25, CCR 1717[f])

Yes No N/A

For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (21 CFR 1306.25, CCR 1717[f])

COMMENTS: _____

_____

15. Confidentiality of Prescriptions

All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

The pharmacy ensures that electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the pharmacy maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4)

COMMENTS: _____

_____

16. Medication Errors

Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

COMMENTS: _____

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17. Recordkeeping Requirements

A completed biennial pharmacy self-assessment form is on file. (CCR 1715)

All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include: prescription records, invoices, US official order forms—DEA Form-222 (Drug Enforcement Administration), power of attorney (21 CFR 1305.07), theft and loss reports (DEA Form-106, 21 CFR 1301.74[c]), biennial controlled substances inventories (21 CFR 1304.11), transfers or sales to other pharmacies and prescribers. (B&PC 4081, 4332, CCR 1718)

Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year, otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11, Prescription Drug Marketing Act of 1987 [Pub.L.100-293, Apr. 22, 1988] 503, B&PC 4160)

A hypodermic log is maintained with complete information for sales of needles and syringes without a prescription. (B&PC 4146)

A controlled substances inventory is completed biennially (every two years). Date completed: _____ (21 CFR 1304.13)

DEA Forms-222 are properly executed. This includes any distribution of Schedule II controlled substances to pharmacies, prescribers, manufacturers and wholesalers. (21 CFR 1305.09)

Yes No N/A

When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2s of the DEA Form-222, properly completed, are submitted at the end of each month to the DEA regional office. (21 CFR 1305.09)

Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)

All dispensed Schedule II triplicate prescriptions conform with all requirements including: directions for use, written entirely in the prescriber's own handwriting, and tendered within seven days following the date of issue. (H&SC 11164, 11166)

All triplicates are submitted to the Department of Justice at the end of each month. (H&SC 11164)

When dispensed upon an "oral" order for a true emergency, the triplicate prescription is received from the prescriber within 72 hours. (H&SC 11167)

Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the pharmacy uses an automated data processing or other recordkeeping system for identification by prescription number and retrieval of original documents. (21 CFR 1304.04[h][2])

Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)

The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or maintains an alternative system for storage and retrieval of the refill information. (21 CFR 1306.22)

Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)

COMMENTS: _____

18. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions

A faxed prescription for a Schedule II controlled substance is dispensed **after** the original written triplicate is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

The pharmacist dispenses an order for a Schedule II controlled substance (from an orally or electronically transmitted prescription) for a patient in a licensed skilled nursing facility, intermediate care facility, or a licensed home health agency providing hospice care, **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated triplicate prescription form. A faxed copy of the prescription, signed by the prescriber, may serve as the original prescription. (21 CFR 1306.11[f], H&SC 11167.5)

The pharmacist maintains records of each partial filling (filled within 30 days from the date of prescription issuance) of an original triplicate prescription for a Schedule II controlled substance written for a diagnosed "terminally ill" inpatient of a skilled nursing facility. (21 CFR 1306.13[b], CCR 1745)

If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. (21 CFR 1306.13[a])

A home infusion pharmacist dispenses a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion on a faxed prescription from the prescriber—the faxed copy of the prescription serving as the

Yes No N/A original written prescription. The pharmacist reduces this prescription to writing on a pharmacy-generated prescription **as long as it is for a patient in a licensed skilled nursing facility, an intermediate care facility, or a licensed home health agency providing hospice care**. (21 CFR 1306.11[e])

Emergency

☐ ☐ ☐ The pharmacist, in an emergency (an accident or calamity) dispenses up to a 72 hours' supply of a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. The pharmacist reduces the prescription to writing and obtains a written triplicate prescription for the controlled substance within 72 hours. (21 CFR 1306.11[d], H&SC 11167)

☐ ☐ ☐ When dispensed upon an "oral" order for a true emergency, the triplicate prescription is received from the prescriber within 72 hours. If the triplicate is not received, the pharmacist informs the Department of Justice within 144 hours of the time the prescription was filled. (H&SC 11167)

COMMENTS: _____

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19. Automated Dispensing

☐ ☐ ☐ The drugs in an automated dispensing unit are properly labeled and identified with at least the following information: name of drug, strength and dosage form, manufacturer and manufacturer's lot number, and expiration date. (21 CFR Part 210, 211, B&PC 4342, H&SC 110105)

COMMENTS: _____

_____

20. Repackaging for Use by the Pharmacy

☐ ☐ ☐ Drugs are repackaged (precounted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer's name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], B&PC 4342, H&SC 110105, 111340)

COMMENTS: _____

_____

21. Compounding Unapproved Drugs for Future Use or Prescriber Office Use

☐ ☐ ☐ Proper records are maintained for the compounding of prescription medications in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription. (CCR 1716.2)

☐ ☐ ☐ Quantities of unapproved drugs compounded for prescriber office use conform with CCR 1716.1.

COMMENTS: _____

_____

Yes No N/A

NUCLEAR PHARMACY

			All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)
			A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

COMMENTS: _____

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